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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,802	09/10/2003	Patrick Fogarty	TOSK-007CON	5245

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EXAMINER	
MONTANARI, DAVID A	
ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,802	FOGARTY, PATRICK	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13-15,18,27,30,31,34 and 42-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 13-15, 18, 27, 30, 31, 34 and 42-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants arguments and amendments filed on 1/7/2009 have been entered.

2. Claims 42-44 are new.

3. Claims 11, 27 and 31 are amended.

4. The 37 CFR 1.132 declaration by Mr. Fogarty has been considered and found persuasive.

5. The 35 USC 102(e) rejection over claims 11, 13-15, 18, 27, 30, 31 and 34 is withdrawn in view of Mr. Fogarty's declaration unequivocally stating that he is the sole inventor of "a single transcriptionally active" flanked by a pair of P-element transposase recognized insertion sequences gene described in U.S. Patent 6, 291, 243 B1.

6. The rejection of claims 11, 13-15, 18, 27, 30, 31 and 34 under 35 USC 112, second parag. is withdrawn in view of Applicants amendments to the claims.

7. Claims 11, 13-15, 18, 27, 30, 31, 34 and 42-44 are examined in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 14, 15, 18, 27, 30, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubin et al. (U.S. Patent 4, 670, 388) and Khillan et al. (1985, Developmental Biology, Vol. 109, pgs. 247-250).

Rubin et al. teach a method of introducing a vector comprising a single transcriptionally active gene (the rosy gene 8.1 kb) that is immediately flanked (less than 1000 bp) by two P-element transposase recognized insertion sequences into any multi-cellular organism (see Abstract, Fig. 1D and col. 6 lines 39-45). Rubin continues to teach that a second vector is used which comprises a DNA sequence encoding transposase that recognizes the target DNA sequences at the termini of the transposon (col. 7 lines 50-54). Rubin does not teach a method of inserting an exogenous nucleic acid into the genome of a rodent.

However, at the time of filing it was known in the art that it was routine to insert exogenous nucleic acids into rodents.

Khillan et al. teach transgenic mice comprising plasmid pπ25.1, which contains the full-length P factor from *Drosophila melanogaster* (pg. 247 col. 1 parag. 2). Khillan continues to teach that said mice were made by micro-injection of said plasmid (linearized) into one-cell mouse embryos (pg. 247 col. 1 last two lines bridge col. 2 lines 1-4). Khillan continues that one newborn from the microinjected embryos was found to carry P element sequences at a concentration of about one copy per mouse genome (pg. 247 col. 2 lines 5-8). Khillan continues that the elegance and success of using P element-mediated gene transfer into *Drosophila* prompted them to look for similar P element integration in the mouse (pg. 247 col. 1 parag. 1 last sentence).

Thus the ordinary artisan would have found it *prima facie* obvious at the time of filing to modify the teachings of Rubin et al. regarding that a single transcriptionally active gene flanked by a pair of P-element transposase recognized insertion sequences can be inserted into any multi-

cellular organism with the teachings of Khillan regarding that the P-element can integrate into the mouse genome and that P-element gene transfer is an elegant and successful method that has much success in *Drosophila*.

Thus the cited art provides the requisite teachings and motivations to make and use the invention as claimed.

Claims 31, 34 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubin et al. (U.S. Patent 4, 670, 388) and Khillan et al. (1985, Developmental Biology, Vol. 109, pgs. 247-250) as applied to claims 11, 14, 15, 18, 27, 30, 42 and 43 above, and further in view of Beall et al. (1998, EMBO J., Vol. 17(2), pgs. 2122-2136).

The specification on pg. 3 lines 14-16 teaches that the P-element transposase recognized insertion sequences are P-element derived 31 bp inverted repeats.

Rubin et al. and Khillan et al. in combination teach that it would have been obvious at the time of filing to insert exogenous nucleic acid into the genome of a rodent comprising introducing a P-element derived vector comprising a single transcriptionally active gene that is flanked by two P-element transposase recognized insertion sequences. Neither Rubin et al. or Khillan et al. teach using a P-element transposase recognized 31 bp insertion sequence.

However at the time of filing it was known to be routine in the art that 31 b P-element transposase recognized insertion sequences are effective to transpose an exogenous gene.

Beall et al. teach that 150 bp of DNA is required at each end of the P-element for efficient transposition to occur *in vivo* and that this region contains the terminal 31 bp inverted repeats (pg. 2122 col. 2 parag. 3 lines 10-16). Beall continues to teach that the 31 bp inverted

repeats are critical for P-element transposition to occur *in vivo* (pg. 2127 col. 1 parag. 2 last 4 lines bridge col. 2 lines 1-2).

Thus the ordinary artisan would have found it *prima facie* obvious at the time of filing to use the 31 bp inverted repeats taught by Beall et al. in a method of inserting an exogenous nucleic acid into a rodent as taught by Rubin and Khillan, given the teachings and motivations by Beall that the 31 bp inverted repeats are essential for P-element transposition to occur *in vivo*.

Thus the cited art provides the requisite teachings and motivations to make and use the invention as claimed.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rubin et al. (U.S. Patent 4, 670, 388) and Khillan et al. (1985, Developmental Biology, Vol. 109, pgs. 247-250) as applied to claims 11, 14, 15, 18, 27, 30, 42 and 43 above, and further in view of Fogarty et al. (U.S. Patent 6, 291, 243 B1).

Rubin et al. and Khillan et al. in combination teach that it would have been obvious at the time of filing to insert exogenous nucleic acid into the genome of a rodent comprising introducing a P-element derived vector comprising a single transcriptionally active gene that is flanked by two P-element transposase recognized insertion sequences. Neither Rubin et al. or Khillan et al. teach a single vector encoding a transposase encoding domain and a single transcriptionally active gene that is flanked by two P-element transposase recognized insertion sequences.

However at the time of filing it was known it the art that it was routine to also include the transposase encoding domain in a P-element vector.

Fogarty et al. teach that P-element derived vectors can comprise both a P-element transposase encoding domain and the region of DNA flanked by the P-feet (transposase recognized insertion sequences (col. 4 lines 11-30).

Thus the ordinary artisan would have found it *prima facie* obvious at the time of filing to use a vector comprising both a transposase encoding domain and single transcriptionally active gene flanked by a pair of P-element transposase recognized insertion sequences given the teachings and motivation by Fogarty that this is routine inclusion in a P-element vector and further in view of the teachings and motivations of Rubin and Khillan regarding a method of inserting an exogenous nucleic acid into a rodent.

Thus the cited art provides the requisite teachings and motivations to make and use the invention as claimed.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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